REMARKS

Claims 1-36 were originally pending in the present Application. In response to a Restriction Requirement, Claims 1-31 were elected for prosecution, while Claims 32-36 have been withdrawn by the Examiner from further consideration. Accordingly, the present PTO Action is directed only to the elected claims, Claims 1-31.

In the Official Action, the Examiner has rejected Claims 11, 14-16, 19, 21-24 and 30 as unpatentable under 35 U.S.C. 103(a) in view of U.S. Patent No. 6,143,778 to Gautier ("Gautier"). The Examiner has indicated that Claims 1-10 and 26-29 are allowable, while Claims 12, 13, 17, 18, 20, 25 and 31 stand objected to as dependent upon rejected claims.

Claims 11, 16, 19, 24, 30 have each been amended to add the limitation from objected to dependent claims (e.g., Claims 12 and 17, now canceled) which require the solution to have a "pH within the range of from about 2.9 to about 3.2." The amendments were made only to expedite the issuance of claims that the Examiner has already indicated are allowable in independent form. The scope of original Claims 11, 16, 19, 24 and 30 is being considered for continued prosecution in a subsequent application(s).

Applicants respectfully disagree with the Examiner's position on the rejected claims. These original claims distinguish over the Gautier disclosure by requiring a concentrated premix ready for intravenous administration without dilution. Gautier discloses an amiodarone composition concentrate for parenteral delivery **after** dilution. The disclosed composition requires a physiologically acceptable buffer solution capable of solubilizing the active principle and of maintaining the pH of the concentrated composition between 2.4 and 3.8 (see column 4, lines 8-54). Gautier discloses an amiodarone hydrochloride formulation "which is at the same time concentrated, stable and dilutable." (See column 1, lines 28-31, column 3, lines 34-39, and lines 47-56). Gautier focuses on the stability and admixing of the concentrate, not a premix. The invention of this application provides a premixed amiodarone hydrochloride formulation which does not require dilution and does not utilize a buffer, not even for solubilizing the active, before parenteral administration to a patient.

Discussion regarding diluted amiodarone concentrations (i.e., admixtures) are set forth by Gautier, but no information is provided that discusses the long-term stability (1 year or more) of the diluted product (see column 5, lines 32-51). In the examples of a diluted form of the amiodarone, Gautier teaches pH levels of around 4 (see examples 2, 4, and 6 of Table, column 6, lines 45-53). Gautier fails to appreciate the importance of a limited pH range of from about 2.9 to about 3.2, and preferably a pH of about 3.1 for long term stability and container compatibility of a diluted premix formulation. By focusing on the stability of a concentrate which is capable of dilution for immediate use or discard, Gautier ignores the potential long term stability problems of the diluted product. That is, outside of the very narrow pH range, problems with drug degradation, particle formation, impurity formation, and container incompatibility can result. By addressing and solving these problems, the premix formulation of the present invention differs from the Gautier disclosure of both a concentrate and a diluted admix product.

CONCLUSION

Claims 1-11, 13-16, and 18-31 are currently pending in the present application. Claims 1-10 and 26-29 have been indicated as allowable. Claims 12, 13, 17, 18, 20, 25 and 31 have also been indicated as allowable if rewritten in independent form. Accordingly, Claims 11, 16, 19, 24 and 30, which were previously rejected under 35 U.S.C. 103(a), have been amended to include the limitation of these objected claims. Applicants have only amended the claims to expedite issuance of the allowed claims, but reserve all rights to further contest the 103(a) rejections in a continuation application. Claims 12 and 17 have been canceled to prevent redundancy.

All claims are considered to be in condition for allowance, and a notice to that effect is earnestly sought at the Examiner's earliest convenience. Should any issues remain in the present application that may be readily addressed by an examiner's amendment, the Examiner is asked to contact the undersigned by phone.

Respectfully submitted,

Date: January 22, 2004

By: _____

Robert W. Diehl, Reg. No. 35,118
Wallenstein Wagner & Rockey, Ltd.
311 S. Wacker Drive, 53rd Floor
Chicago, Illinois 60606-6630
312.554.3300

Express Mail Label No. EV381276253US
Date of Deposit: January 22, 2004
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Mail Stop FEE AMENDMENT, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Sarah J. Goodnight (187883.1)